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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,874	01/17/2006	Hiroyuki Shimoji	SAEG124.005APC	3870
20995 7590 12/08/2010 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER ORKIN, ALEXANDER J	
			ART UNIT 3773	PAPER NUMBER
			NOTIFICATION DATE 12/08/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/564,874	Applicant(s) SHIMOJI ET AL.	
	Examiner ALEXANDER ORKIN	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/21/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1 A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/22/2010 has been entered.

Claim Rejections - 35 USC § 103

2 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3 The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4 Claims 1, 3, 4, 6, 10-14 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,766,188 to Igaki in view of U.S. Patent 2,811,299 to Swanson.

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As to claims 1, 6, 10 Igaki discloses a tubular suture reinforcement material and the method of making the material by stacking two sheet-like materials and sewing together both ends using two stitches, and combining the two sheets of materials by sewing two opposite sides to create the tubular structure. However Igaki lacks the two chain stitches and that the thread end passes through loop next to the sewing end which is continuous to the thread end and returned to the sewing end after passing the through the loop next to the sewing end. Instead they disclose a normal stitch. However it is commonly known in the art to use a chain stitch.

Swanson teaches using a chain stitch, where the chain stitches comprises a plurality of loops in which one of the loops passes through an adjacent loop in a direction away from a sewing end, on an open material to be able to releasably close it using one stitch. The stitch has each loop going through the prior loop just like how the chain stitch is defined in this application additionally, the ends of the threads have a loop next to the sewing end that does not pass through the loop next to the sewing end (Fig 1, col. 3, ll. 30-43) (Fig. 4). Swanson further discloses the thread end (tuck back) passes through the loop next to the sewing end continuous with the threaded thereby preventing unraveling without tying a knot at the sewing end (Fig. 4, col. 2, ll. 40-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stitch of Igaki with the chain stitch of Leopold in order to better prevent unwanted unraveling.

As to claim 3, with the invention of Igaki and Swanson above, Igaki further discloses the material of the tubular suture reinforcement material being made up from a biodegradable and bioabsorbable knitted, woven, unwoven fabric etc (col. 3, ll. 1-12).

As to claim 4, with the invention of Igaki and Swanson above, Igaki discloses that these materials can be stacked on top of each other with one of them being stretchable in order to make the tubular shape (col. 3, ll. 1-12).

As to claim 11, with the invention of Igaki and Swanson above, Igaki further discloses the automatic suture device comprising a cartridge with staples and a frame that has a staple receiving slot wherein a tubular suture reinforcement material for an automatic suturing device is fitted to the cartridge and/or frame (Fig. 5).

As to claim 12, with the invention of Igaki and Swanson above, Igaki discloses the method of removing an affected part of a tissue, which could be a lesion from a patient by first sandwiching the tissue in the unwoven fabrics. The tissue is then separated by a cutter. Finally the end of the suture is pulled to separate the section remaining in vivo and the section removed. This leaves part of the material inside the body, while removing some of the material along with the affected part (figure 5-7, col. 3 ll. 33-53).

As to claims 13 and 14, with the invention of Igaki and Swanson above, Igaki discloses using this method in either a soft tissue or in a pulmonary tissue (col. 4, ll. 53-59).

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5 Claims 1, 3, 4, 6, 10-14 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,766,188 to Igaki in view of U.S. Patent 6,984,242 to Campbell et al.

As to claims 1, 6, 10 Igaki discloses a tubular suture reinforcement material and the method of making the material by stacking two sheet-like materials and sewing together both ends using two stitches, and combining the two sheets of materials by sewing two opposite sides to create the tubular structure. However Igaki lacks the two chain stitches and that the thread end passes through loop next to the sewing end which is continuous to the thread end and returned to the sewing end after passing the through the loop next to the sewing end. Instead they disclose a normal stitch. However it is commonly known in the art to use a chain stitch.

Campbell teaches using a chain stitch, where the chain stitches comprises a plurality of loops in which one of the loops passes through an adjacent loop in a direction away from a sewing end, on an open material to be able to releasably close it using one stitch. The stitch has each loop going through the prior loop just like how the chain stitch is defined in this application additionally, the ends of the threads have a loop next to the sewing end that does not pass through the loop next to the sewing end (Fig 3 a,b,) . Swanson further discloses the thread end (tuck back) passes through the loop next to the sewing end continuous with the threaded thereby preventing unraveling without tying a knot at the sewing end (Fig. 4, col. 17, ll. 32- col.18 ll. 4). It would have been obvious to one of

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ordinary skill in the art at the time the invention was made to modify the stitch of Igaki with the chain stitch of Leopold in order to better prevent unwanted unraveling.

As to claim 3, with the invention of Igaki and Campbell above, Igaki further discloses the material of the tubular suture reinforcement material being made up from a biodegradable and bioabsorbable knitted, woven, unwoven fabric etc (col. 3, ll. 1-12).

As to claim 4, with the invention of Igaki and Campbell above, Igaki discloses that these materials can be stacked on top of each other with one of them being stretchable in order to make the tubular shape (col. 3, ll. 1-12).

As to claim 11, with the invention of Igaki and Campbell above, Igaki further discloses the automatic suture device comprising a cartridge with staples and a frame that has a staple receiving slot wherein a tubular suture reinforcement material for an automatic suturing device is fitted to the cartridge and/or frame (Fig. 5).

As to claim 12, with the invention of Igaki and Campbell above, Igaki discloses the method of removing an affected part of a tissue, which could be a lesion from a patient by first sandwiching the tissue in the unwoven fabrics. The tissue is then separated by a cutter. Finally the end of the suture is pulled to separate the section remaining in vivo and the section removed. This leaves part of the material inside the body, while removing some of the material along with the affected part (figure 5-7, col. 3 ll. 33-53).

As to claims 13 and 14, with the invention of Igaki and Campbell above, Igaki discloses using this method in either a soft tissue or in a pulmonary tissue (col. 4, ll. 53-59).

6 Claim 2 is rejected under 3/ U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,766,188 to Igaki in view of U.S. Patent 2,811,299 to Swanson in further view of U.S. Patent No. 6,063,097 to Oi et al.

As to claim 2, Igaki and Swanson teach the tubular suture reinforcement material above in claim 1, but they lack the tapered end.

Oi teaches the tubular reinforcement material having the tip part sewed in a tapering fashion (Fig. 7). It would have been obvious to one of ordinary skill of the art to modify the tip part of the material of Igaki and Swanson to make be sewn in a tapered manner as taught by Oi in order to prevent turnup of the supporting element.

7 Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,766,188 to Igaki in view of U.S. Patent 2,811,299 to Swanson in further view of U.S. Patent No. 6,273,897 to Dalessandro et al.

As to claim 5, and Swanson teach the tubular suture reinforcement material above in claim 1 but they lack the projections on the sewing portion of the reinforcement material.

Dalessandro teaches projections on a buttress or a suture reinforcement material. These projections can make it easier to slide the buttress onto the instrument (Fig 12, 13a, 13b, col. 3, ll. 50-2). This same function of using the

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projections to make it easier to slide a device on the instrument can be used with Igaki and Swanson in loading the suture reinforcement material onto the instrument. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify tubular structure of Igaki with the projection of Dalessandro in order to make it easier to load the tubular suture reinforcement material onto the automatic suturing device.

Response to Arguments

8 Applicant's arguments filed 09/22/2010 have been fully considered but they are not persuasive. The applicant argues that the prior art reference Swanson teaches a different mechanism for preventing the thread for unraveling specifically when the mechanism is applied during the process of stitching, and that the mechanism has a much tighter strength that it won't be smoothly removed. However, having the thread being smoothly removed is not in the claims. Further limitations about the strength of the prevention of unraveling or when the mechanism is applied is needed in the claims in order to overcome the prior art of reference.

9 Of Note: Prior art Campbell was used in non-final office action dated 09/18/2008, and the remarks on 12/18/2008 argued that Campbell did not have a mechanism of prevention of the thread unraveling (pg 6). Upon further consideration, Campbell does teach the loop next to the sewing end does not pass through an another loop anterior the loop next to the sewing end, and a thread end at the sewing end passes through a loop next to the sewing end to prevent unraveling (figure 4 col. 17 ll. 32- col. 18 ll. 4).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER ORKIN whose telephone number is (571)270-7412. The examiner can normally be reached on Monday-Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. O./
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773